DEC 14 2005

K053097

BIOMÉRIEUX

510(k) SUMMARY

VITEK® 2 Gram Positive Cefoxitin Screen

510(k) Submission Information:

Submitter's Name:	bioMérieux, Inc.
Address:	595 Anglum Road Hazelwood, MO 63042
Contact Person:	Nancy Weaver Staff Regulatory Affairs Specialist
Phone Number:	314-731-8695
Fax Number:	314-731-8689
Date of Preparation:	October 31, 2005

B. Device Name:

Formal/Trade Name:	VITEK® 2 Gram Positive Cefoxitin Screen
Classification Name:	Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility Device, 21 CFR 866.1645
Common Name:	VITEK 2 Cefoxitin Screen (OXSF)

C. Predicate Device: VITEK 2 Gram Positive AST for High-Level Streptomycin (N50510/S113)

D. 510(k) Summary:

VITEK® 2 Gram Positive Cefoxitin Screen is a qualitative test designed to predict *mec*A-mediated resistance in staphylococci. It is intended for use with the VITEK® 2 and VITEK® 2 Compact Systems as a laboratory aid in the determination of *in vitro* susceptibility to antimicrobial agents. The antimicrobial presented in VITEK 2 AST Cards is in concentrations equivalent by efficacy to standard method concentrations in µg/ml. The VITEK 2 AST Cards are essentially miniaturized versions of the doubling dilution technique for determining the minimum inhibitory concentration (MIC) microdilution methodology.

The bacterial isolate to be tested is diluted to a standardized concentration in 0.45% saline before being used to rehydrate the antimicrobial medium within the card. The VITEK 2 automatically fills, seals and places the card into the incubator/reader. The VITEK 2 Compact has a manual filling and sealing operation. The VITEK 2 monitors the growth of each well in the card over a defined period of time (up to 18 hours). At the completion of the incubation cycle, a report is generated. For the VITEK 2 Cefoxitin Screen the report will list either a positive or negative test result.

VITEK 2 Cefoxitin Screen demonstrated substantially equivalent performance when compared with the CLSI reference method, disk diffusion test for prediction of mecA-mediated resistance in staphylococci.

The Premarket Notification (510[k]) presents data in support of VITEK 2 Gram Positive Cefoxitin Screen. An external evaluation was conducted with fresh and stock clinical isolates and stock challenge strains. The external evaluations were designed to confirm the acceptability of VITEK 2 Cefoxitin Screen by comparing its performance with the CLSI disk diffusion test. The data is representative of performance on both the VITEK 2 and VITEK 2 Compact instrument platforms, as evidenced in the AST equivalency study presented in the VITEK 2 Compact file, K050002. VITEK 2 Gram Positive Cefoxitin Screen demonstrated acceptable performance of 97.2% overall Category Agreement. Reproducibility and Quality Control demonstrated acceptable results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 14 2005

Ms. Nancy Weaver
Staff Regulatory Affairs Specialist
bioMérieux, Inc.
595 Anglum Road
Hazelwood, MO 63042-2320

Re: k053097
Trade/Device Name: VITEK® 2 Gram Positive Cefoxitin Screen (6 µg/ml)
Regulation Number: 21 CFR 866.1645
Regulation Name: Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility Devices
Regulatory Class: Class II
Product Code: LON
Dated: October 31, 2005
Received: November 3, 2005

Dear Ms. Weaver:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053097

Device Name: VITEK® 2 Gram Positive Cefoxitin Screen (6 µg/ml)

Indications For Use:

VITEK® 2 Gram Positive Cefoxitin Screen is a qualitative test designed to predict mecA-mediated resistance in staphylococci. It is intended for use with the VITEK® 2 and VITEK® 2 Compact Systems as a laboratory aid in the determination of in vitro susceptibility to antimicrobial agents.

The VITEK® 2 Antimicrobial Susceptibility Test (AST) is intended to be used with the VITEK® 2 and VITEK® 2 Compact Systems for the automated quantitative or qualitative susceptibility testing of isolated colonies for the most clinically significant aerobic gram-negative bacilli, *Staphylococcus spp.*, *Enterococcus spp.*, *Streptococcus agalactiae*, and *S. pneumoniae*.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K053097